

II. REMARKS

The Office Action dated November 8, 2007, has been received and carefully noted. The amendments made herein and the following remarks are submitted as a full and complete response thereto.

Claims 23-25, 27, 29, 31-66, and 68-78 are pending. Claims 24, 27, 29, 34, 36, 59, 60, 62, and 74 have been withdrawn from consideration.

By this Amendment, claims 23, 25, 35, 37, 38, 44, 47, 68-70, 73, and 75 are amended. Support for the amendment can be found in the specification and claims as originally filed. For example, claims 23, 25, 44, 47, 68-70, 73, and 75 have been amended to remove language and clarify the definition of the variables. Claims 35, 37, and 38 have been amended, at the Examiner's request, to move claim language to a different part of the claim. Applicants submit that no new matter has been added and respectfully request reconsideration and withdrawal of all pending claims.

Rejection under 35 U.S.C. §112, second paragraph

Claims 23, 25, 31-33, 35, 37-50, 52-57, 68-70, 75, 77 and 78 are rejected under 35 U.S.C. §112 second paragraph, as being indefinite. In light of the amendments to the claims, Applicants traverse the rejection.

In response to the Examiner's rejection, Applicants have amended claims 23, 25, 35, 37, 38, 44, 47, 68-70, and 73. However, Applicants disagree with the Examiner's assertion that "the variable 'R' is defined in two different ways" in claim 75 (and therefore also in dependent claims 77-78).

Further, Applicants submit that although claims 53 and 57 were rejected under 35 U.S.C. § 112, second paragraph, the reason for the rejection is unclear because the Examiner has not asserted a reason. Applicants request clarification about the rejection of claims 53 and 57.

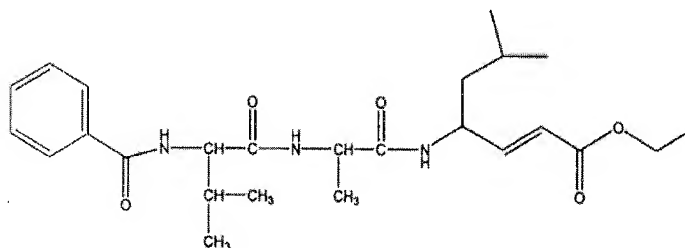
In light of the amendments, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 23, 25, 31-33, 35, 37-50, 52-57, 68-70, 75, 77 and 78 under 35 U.S.C. §112 second paragraph.

Rejections under 35 U.S.C. § 102

1. Johnson *et al.*

Claims 23, 25, 44, 47, 53, 68-70, 73 and 75 are rejected under 35 U.S.C. 102(a) as being anticipated by Johnson (WO 97/04004). Applicant traverse the rejection.

As noted by the Examiner, Applicants submit that Johnson *et al.* discloses the following compound:



wherein, corresponding to the present invention, R₁ is benzoyl, R₂ is hydrogen, R₃ is methyl, R₄ is methyl, and R₅ is hydrogen, R₆ is hydrogen, R₇ is methyl, and R₈ is hydrogen (Johnson *et al.*, compound 26, page 74).

Applicants submit that claims 23, 25, 44, 47, 53, 68-70, 73 and 75 are not taught or

suggested by Johnson et al. For example, in contrast to Johnson et al., wherein R₁ is benzoyl, Applicants submit that present claims 23, 25, 44, 47, 68-70, and 73 are directed to a compound or pharmaceutically acceptable salt thereof of formula (I), wherein “R₁ and R₂ are independently selected from the group consisting of: H and a saturated or unsaturated moiety having a linear, branched, or non-aromatic cyclic skeleton...” (emphasis added).

Applicants submit that claim 53 of the presently claimed invention is directed to a compound or pharmaceutically acceptable salt thereof in which “R₇ is a three to six carbon atom, branched alkyl group” (emphasis added). In contrast, Johnson et al. discloses a compound in which the corresponding R₇ is methyl.

Applicants submit that claim 75 of the presently claimed invention is directed to a compound or pharmaceutically acceptable salt thereof in which “R₁ and R₂ are selected from the group consisting of H and a saturated or unsaturated moiety having a linear, branched, or non-aromatic cyclic skeleton...” In contrast, Applicants submit that Johnson et al. discloses a compound in which the corresponding R₁ is benzoyl.

As such, as Johnson et al. fails to teach or suggest all of the elements of the presently claimed invention, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 23, 25, 44, 47, 53, 68-70, 73 and 75 under 35 U.S.C. § 102(a) over Johnson et al.

2. Falender et al.

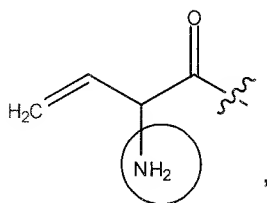
Claims 23, 25, 31, 44, 47, 53, 68-70, 73, and 75 were rejected under 35 U.S.C. §102(b) as being anticipated by Falender et al. (*Biocatalysis and Biotransformation* 13(2), 131-139, 1995). Applicants traverse the rejection.

As noted by the Examiner, Applicants submit that Falender et al. discloses the following compound:



wherein, corresponding to the presently claimed invention, R₁ is allylglycine, R₂ is hydrogen, R₃ is phenyl, R₄ is hydrogen, R₅ is hydrogen, R₆ is hydrogen, R₇ is benzyl, and R₈ is hydrogen.

In contrast, Applicants submit that claims 23, 25, 31, 44, 47, 53, 68-70, 73 and 75 are not taught or suggested by Falender et al. For example, present claims 23, 25, 44, 47, 68-70, and 73 are directed to a compound or pharmaceutically acceptable salt thereof of formula (I), wherein "R₁ and R₂" are independently selected from the group consisting of: H and a saturated or unsaturated moiety having a linear, branched, or non-aromatic cyclic skeleton containing one to ten carbon atoms, and the carbon atoms are optionally substituted with: -OH, -I, -Br, -Cl, -F, -CN, -CO₂H, -CHO, -COSH, or -NO₂. As mentioned above, Falender et al. discloses that R₁ is allylglycine and R₂ is hydrogen. Applicants note that allylglycine has the following structure:



wherein, as circled, the moiety is substituted with -NH₂. Applicants submit that the compounds of present claims 23, 25, 44, 47, 68-70, and 73 are not directed to compounds in which R₁ or R₂ is substituted with -NH₂.

Applicants submit that claim 31 is directed to a compound or pharmaceutically acceptable salt thereof in which "R₃ and R₄ are independently selected from the group consisting of: methyl, ethyl, n-propyl and n-butyl" and "R₅ is selected from the group consisting of: H, R, ArR-, and Ar" (emphasis added). In contrast, Falender et al. discloses a compound in

which the corresponding R₃ is phenyl, and R₄ and R₅ are both hydrogen.

Further, Applicants submit that claim 53 is directed to a compound in which "R₇ is a three to six carbon atom, branched alkyl group" (emphasis added). In contrast, Falender et al. discloses a compound in which the corresponding R₇ is a benzyl group.

Applicants submit that claim 75 of the presently claimed invention is directed to a compound or pharmaceutically acceptable salt thereof in which "R₁ and R₂ are selected from the group consisting of H and a saturated or unsaturated moiety... containing one to ten carbon atoms...and the carbon atoms are optionally substituted with -OH, -I, -Br, -Cl, -F, -CN, -CO₂H, -CHO, -COSH, and -NO₂." In contrast, Applicants submit that Johnson et al. discloses a compound in which the corresponding R₁ is allylglycine, which is a moiety containing -NH₂.

As such, as Falender et al. does not teach or suggest all of the elements of the presently claimed invention, Applicants request reconsideration and withdrawal of the rejection of claims 23, 25, 31, 44, 47, 53, 68-70, 73 and 75 under 35 U.S.C. § 102(b) over Falender et al.

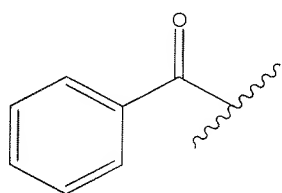
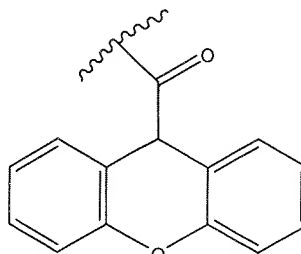
Rejections under 35 U.S.C. § 103

1. Johnson et al.

Claims 23, 25, 44, 47, 53, 68-70, 73, 75, 77, and 78 are rejected under 35 U.S.C. §103 as being unpatentable over Johnson et al. (WO 97/04004).

Applicants have discussed the differences between the presently claimed invention and the compound disclosed in Johnson et al. above. Applicants submit that the compounds and pharmaceutically acceptable salts thereof disclosed in present claims 23, 25, 44, 47, 53, 68-70, 73, 75, 77 and 78 are not structurally similar to the compound disclosed in Johnson et al. As

such, Applicants submit that one of ordinary skill in the art would not be motivated to modify the compound disclosed in Johnson et al. to arrive at the presently claimed invention without the benefit of hindsight. For example, compound 26 of Johnson et al. and compound 34 of Johnson et al., which was previously cited against the present application, both require bulky ring structures at the R₁ and R₂ positions:

R₁ Johnson et al. Compound 26R₁ Johnson et al. Compound 34

In contrast, in present claims 23, 25, 44, 47, 53, 68-70, and 73, R₁ and R₂ are selected from “the group consisting of: H and a saturated or unsaturated moiety having a linear, branched, or non-aromatic cyclic skeleton containing one to ten carbon atoms...” (emphasis added).

Similarly, present claim 75 is directed to a compound or pharmaceutically acceptable salt thereof in which “R₁ and R₂ are selected from the group consisting of H and a saturated or unsaturated moiety having a linear, branched, or non-aromatic cyclic skeleton...” Claims 77 and 78 depend from claim 75.

As such, Applicants submit that Johnson et al. does not teach or suggest modifying the compound disclosed in Johnson, particularly R₁ and R₂, by replacing the bulky ring structures with the R₁ and R₂ structures of the presently claimed invention.

For at least the above reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 23, 25, 44, 47, 53, 68-70, 73, 75, 77 and 78 under 35

U.S.C. § 103 over Johnson *et al.*

2. Falender *et al.*

Claims 23, 25, 31, 44, 47, 53, 68-70, 73, 75, 77, and 78 are rejected under 35 U.S.C. §103 as being unpatentable over Falender *et al.* Applicants traverse the rejection.

Applicants have discussed the differences between the compound disclosed in Falender *et al.* and the presently claimed invention above. Applicants submit that present claims 23, 25, 31, 44, 47, 53, 68-70, 73, 75, 77 and 78 are patentable over Falender *et al.*, because without the benefit of hindsight, one of ordinary skill in the art would not be motivated to modify the compound disclosed in Falender *et al.* to arrive at the presently claimed invention. In particular, Applicants submit that Falender *et al.*, which is merely directed to the synthesis of tetrapeptide ethylesters, fails to provide guidance as to which groups are necessary to impart biological activity, a property of the presently claimed compounds and pharmaceutically acceptable salts thereof (see specification, page 12, line 20). Applicants submit that since Falender *et al.* does not teach or suggest how such properties can be attained, there can be no motivation to modify this reference towards Applicants' solution.

For at least the above reasons, Applicants respectfully request reconsideration and withdrawal of the rejection of claims 23, 25, 31, 44, 47, 53, 68-70, 73, 75, 77 and 78 under 35 U.S.C. § 103 over Falender *et al.*

III. CONCLUSION

In view of the amendments and remarks above, Applicants respectfully submit that this application is in condition for allowance and request favorable action thereon. If the Examiner believes that anything further is desirable in order to place this application in even better condition for allowance, the Examiner is invited to contact Applicants' undersigned representative at the telephone number listed below to discuss any remaining issues.

Any additional fees that are required with respect to this response may be charged to Deposit Account No. 01-2300, referencing Attorney Docket No. 108281-00000.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'YK', is written over a horizontal line.

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